

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

THE CITY OF HUNTINGTON,

Plaintiff,

v.

AMERISOURCEBERGEN DRUG
CORPORATION, et al.,

Defendants.

Civil Action No. 3:17-01362
Hon. David A. Faber

CABELL COUNTY COMMISSION,

Plaintiff,

v.

AMERISOURCEBERGEN DRUG
CORPORATION, et al.,

Defendants.

Civil Action No. 3:17-01665
Hon. David A. Faber

**DEFENDANTS’ NOTICE OF SUPPLEMENTAL AUTHORITY IN OPPOSITION TO
PLAINTIFFS’ MOTION FOR PARTIAL SUMMARY JUDGMENT CONCERNING
DEFENDANTS’ STATUTORY AND REGULATORY DUTIES**

Defendants respectfully submit this notice of supplemental authority in support of their Opposition to Plaintiffs’ Motion for Partial Summary Judgment Concerning Defendants’ Statutory and Regulatory Duties (“Opposition” or “Opp.,” Dkt. No. 1079). On November 2, 2020, the Drug Enforcement Administration (“DEA”) published a notice of proposed rulemaking that confirms that the federal Controlled Substances Act (“CSA”) and its implementing regulations do not contain a “no-shipping” duty. This directly supports the argument made in Defendants’ Opposition that neither the CSA nor its West Virginia counterpart currently require or required in the past Defendants to block “suspicious orders” pending investigation. Opp. at 4–15.

In its proposed regulation, DEA seeks to “*revise* its regulations relating to suspicious orders.” *See* Ex. 1 (Suspicious Orders of Controlled Substances, 85 Fed. Reg. 69282 (proposed Nov. 2, 2020) (to be codified at 21 C.F.R. pt. 1300, 1301)) at 69282 (emphasis added). The proposed regulation would “adopt[]” what DEA refers to as a “two-option framework,” under which registrants who receive orders under suspicious circumstances must either (1) report the order to DEA and decline to ship the order *or* (2) investigate the order and ship it only if the registrant is able through due diligence to dispel the suspicious circumstances surrounding the order. *See id.* at 69283; *see also id.* at 69288 (“DEA is *amending its regulations* to provide that, upon receipt of an [order received under suspicious circumstances], registrants shall proceed under the following two-option framework”) (emphasis added).¹ These new provisions—proposed for the first time on November 2, 2020—are precisely the “no-shipping” provisions that Plaintiffs erroneously argue already are contained in the current regulations.

By proposing a new rule that includes—for the first time—“no-shipping” language, DEA has confirmed that a purported “no-shipping” duty is *not* part of the existing regulatory scheme. As DEA recognizes in the Notice of Proposed Rulemaking, the existing regulations address only the identification and *reporting* of suspicious orders:

The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant.

See 21 C.F.R. § 1301.74(b); Ex. 1 at 69286. By contrast, the proposed regulations state:

(a) Upon receipt of an order received under suspicious circumstances, the registrant shall proceed under one of the following two options:
 (1) The registrant *shall decline to distribute* pursuant to the suspicious order, immediately file a suspicious order report through the DEA centralized database (which includes the information described in paragraph

¹ DEA further proposes, also for the first time, to add a definition of “due diligence” and to set forth the circumstances under which distributors must conduct due diligence. *See* Ex. 1 at 69298.

- (b) of this section), and maintain a record of the suspicious order and any due diligence related to the suspicious order (which includes at least the information described in paragraph (c) of this section); **or**
- (2) The registrant, ***before distributing*** pursuant to the order received under suspicious circumstances, ***shall conduct due diligence*** to investigate each suspicious circumstance surrounding the order.

See Ex. 1 at 69298 (emphasis added). While DEA suggests that this “no-shipping” rule would “formalize current business practices” and is “consistent” with the *Masters* and *Southwood* decisions, *id.* at 69292, there would be no need for DEA to “amend” or “revise” its existing regulations to add no-shipping language if the current regulations already included a no-shipping requirement. *See, e.g., Himes v. Thompson*, 336 F.3d 848, 860 (9th Cir. 2003) (noting that an amendment purportedly clarifying parole board’s authority under earlier rule to release prisoners early “would not have been necessary” if the earlier rule were properly interpreted to grant the parole board that authority). Tellingly, DEA ***does not*** suggest that the “no-shipping” language or the “two-option framework” are actually set forth in the existing regulations.

In short, DEA’s new proposed regulation is further authority for Defendants’ Opposition (Dkt. No. 1079, at 4–15)—namely, that wholesale distributors do not have an obligation under the existing regulatory scheme to refuse to ship suspicious orders.

Dated: November 9, 2020

Respectfully Submitted,

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CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that on this 9th day of November, 2020, the foregoing “DEFENDANTS’ NOTICE OF SUPPLEMENTAL AUTHORITY IN OPPOSITION TO PLAINTIFFS’ MOTION FOR PARTIAL SUMMARY JUDGMENT CONCERNING DEFENDANTS’ STATUTORY AND REGULATORY DUTIES” was served using the Court’s CM/ECF system, which will send notification of such filing to all counsel of record.

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